

REMARKS/ARGUMENTS

Claims 1-20 are currently pending in the present application. Claims 1-20 were rejected. By this amendment, claims 1, 6 and 16 are amended. Applicant submits that such amendments place the claims in condition for allowance.

Applicant's Invention

The instant invention provides an impact resistant substrate juxtaposed in close spatial relationship to the back of the wearer's neck. The rigid substrate¹ provides protection to the wearer's spine in the event the user falls back against a curb, rail or other protrusion during cycling, roller blading, or the like. The art of record does not anticipate or suggest this rigid protection.

Lipton's Device is Not Impact Resistant

Claims 1-3 and 16 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lipton, U.S. Patent No. 4,891,501 (hereinafter "*Lipton*"). Claims 1 and 16 have been amended² to more clearly define Applicant's invention. Applicant respectfully submits that the §102(b) rejection of claims 1-3 and 16 has been overcome and the pending claims are allowable.

Anticipation under 35 U.S.C. §102(b) requires "the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim."³ Applicant submits that *Lipton* does not discloses each and every element of claims 1 and 16 as now more clearly defined.

The Office Action provides that *Lipton* discloses:

a protective neck device including a first impact resistant pliable arcuate substrate adapted to encircle the neck and lower cranium with adjustable straps (114) having hook and loop material that extends from the substrate and worn about the neck as shown in figures 1, 3 and 6. Further, the device

¹ See, for example, Specification, page 5, line 25.

² Support for the amendments to claims 1 and 16 may be found at, for example, page 2, line 17-18 and page 2, line 25 – page 4, line 23

³ *Lindermann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)).

has a second substrate that is integrally molded to the first substrate with cold/hot packs being positioned therebetween, col. 3, line 1 – col. 4, line 66. Further, a rigid planar substrate is attached to the device, col. 3, lines 10-12.⁴

Applicant respectfully disagrees.

Lipton specifically discloses a “therapeutic treatment pad”⁵ and a “therapeutic pad”⁶ for “the therapeutic treatment of injured muscles.”⁷ *Lipton* does not teach, or even suggest, a “device to protect the neck and the base of the skull of a person from injury during physical activities” as recited by amended claim 1 among other features or a “device for imparting physical protection and predetermined temperature to the human neck during physical activity” as recited by amended claim 16, among other features.

Lipton also specifically discloses a therapeutic pad having “a first layer of soft cloth or other flexible material, such as terrycloth”⁸ and “vinyl or a similar flexible plastic material.”⁹ *Lipton* does not teach or suggest “a first impact-resistant pliable substrate” as recited by amended claim 1 among other features or “a first impact-resistant substrate” as recited by amended claim 16 among other features. As *Lipton* does not teach, or otherwise suggest, each and every element of the claimed invention, the §102(b) rejection of claims 1 and 16 is overcome.

Claims 2 and 3 depend from claim 1 and include all of the limitations thereof. The rejection of claims 2 and 3 based on *Lipton* is overcome for all the reasons provided above for claim 1.

Furthermore, to constitute a proper anticipatory reference under §102(b), the reference must generally place the subject matter supporting the anticipatory rejection in the public domain before the date of the invention. For example, the CCPA has stated:

[f]or a publication to constitute an anticipation of an invention and, thus, to bar the grant of a patent under 35 USC 102, it must be capable, when taken in conjunction with the

⁴ Office Action, ¶2, page 2, lines 9-14.

⁵ See for example *Lipton*, Title; col. 1, lines 10-11; and col. 1, line 55.

⁶ See for example *Lipton*, Abstract; col. 1, line 59; and col. 2, line 46.

⁷ *Lipton*, col. 1, lines 16-17.

⁸ *Lipton*, col. 3, lines 3-4.

⁹ *Lipton*, col. 5, lines 8-9.

knowledge of those skilled in the art to which it pertains, of placing the invention in the possession of the public.¹⁰

Applicant respectfully submits that *Lipton* discloses a therapeutic treatment pad for the therapeutic treatment of injured muscles, where the pad has a first layer of soft cloth or other flexible material, such as terrycloth. Only such a disclosed therapeutic treatment pad is placed in the public domain. *Lipton* does not teach or suggest the claimed invention; therefore *Lipton* does not place it in the public domain. For all these reasons, the §102(b) rejection of claims 1-3 and 16 is overcome.

Lipton Soothes Muscles But Does Not Protect/Cushion Bones

Claims 6-15 and 17-20 stand rejected under 35 U.S.C. §103(a) as being anticipated by *Lipton*. Applicant traverses this rejection with respect to claims 6-15 and 17-20 and respectfully submits that the pending claims are allowable.

The Office Action provides that *Lipton* discloses:

[w]ith regard to claims 6-7 and 9-15, it would have been obvious to one skilled in the device of *Lipton* having cold/hot packs are deformable and filled with fluid as known in the art that has a means (308) to regulate flow through the substrate as shown in figure 9. Further, it is obvious that the neck device of *Lipton* extends to a region below the person's seventh vertebra as shown in figure 14.

With regard to claim 8, it would have been obvious that the straps of *Lipton* can be made of any desirable material that was available at the time the device was made.

Furthermore, the first, second and third substrates (16,20,22) of *Lipton* can be made of any desired weight, density, etc. as required for a particular application or end use thereof.¹¹

Applicant respectfully disagrees.

Claims 6-15 and 17-20 depend, directly or indirectly, from amended independent claims 1 and 16 respectively. Each of these dependent claims recite additional features

¹⁰ *In re Donohue*, 632 F.2d 123, 207 USPQ 196, 199 (CCPA 1980) (citing *In re LeGrice*, 301 F.2d 929, 944, 133 USPQ 365, 378 (CCPA 1962) and *In re Brown*, 329 F.2d 1006, 1011, 141 USPQ 245, 249 (CCPA 1964)).

¹¹ Office Action, ¶4, page 3, lines 2-10.

(such as the claimed second substrate) and are therefore believed allowable for all the reasons provided above with respect to claims 1 and 16.

Applicant's second substrate serves as a cushion¹² vis-à-vis the first, relatively harder substrate. This cushion is designed to minimize discomfort caused by the first substrate pressing against bony prominences of the wearer's spine.

The art of record does not disclose a cushion (i.e., the second substrate) because the art of record is only concerned with soft tissue injuries.

It is respectfully submitted that *Lipton* does not disclose each and every element of the dependent claims. The Office Action provides that *Lipton* discloses a device filled with fluid as provided previously. *Lipton* specifically discloses "two identical shaped sheets of vinyl or a similar flexible plastic material, which are heat sealed at their edges to define a sealed volume therein,"¹³ where the sealed volume may receive a fluid for hot or cold treatment of injured muscles.

However, even though *Lipton* discloses a sealed volume that may contain a fluid for hot or cold treatment, *Lipton* does not teach the "the second substrate is less rigid than said first substrate, further said second substrate is adapted to receive fluid second substrate is adapted to receive fluid" as recited by amended claim 6¹⁴, among other features; the "second substrate comprises a plurality of reversibly deformable substrates" as recited by claim 7, among other features; the "second substrate is adapted to removably receive a hot-pack or a cold-pack" as recited by claim 13, among other features; the "first substrate is adapted to reversibly receive a hot-pack or a cold-pack" as recited by claim 15, among other features; or the "cavity defined by a portion of the second substrate, wherein the cavity is adapted to receive the cold packs or hot packs" as recited by claim 18, among other features.

With regard to claim 8, the Office Action submits that the straps may be made of any desired material. Applicant disagrees. *Lipton* discloses treating injured muscle groups using the subject pad. *Lipton* does not suggest, or even contemplate, the need for quick detection of hemorrhaging or other injury. Therefore *Lipton* does not teach or

¹² See for example, Specification, page 7, lines 1-8.

¹³ *Lipton*, col. 5, lines 8-10.

¹⁴ Support for this amendment to claim 6 may be found at, for example, page 7, lines 4-7 and claim 17.

suggest, "the straps are radio-translucent" (to detect fractured bones for example) much less the "first substrate, the second substrate, and the straps are radio-translucent" as recited by claim 8, among other features. This is because *Lipton* is designed to south muscles, not protect bones.

With respect to claim 11, the Office Action provides that the *Lipton* device includes means to regulate flow through the device. Specifically, *Lipton* discloses "small opening 308 or 308' in the portions 306 and 306'"¹⁵ adapted to divide the sealed volume formed by the two identical shaped sheets of vinyl into two segments. However, nothing in *Lipton* teaches or discloses "means for regulating fluid flow through the second substrate" as recited by claim 11, among other features. Rather, *Lipton* merely allows flow between the portions.

With regard to claim 14, the Office Action provides that *Lipton* discloses a device extending below a person's seventh vertebra as provided previously. First, *Lipton* does not have a figure 14 as provided in the Office Action. Applicant can only assume that this is a typographical error and that the Office Action is referring to figure 6 and/or 8. Nevertheless, Applicant submits that *Lipton* does not disclose "extends to a region below the person's seventh vertebra" as recited by claim 14, among other features. Rather, *Lipton* discloses covering:

the Temporalis 202, Masseters 204, Insertion of the Internal Pterygoid 206 and Hyoid muscles 208 are all covered by the pad. Element 210 is the jawbone. The provision of the cut out 10 permits the pad to be positioned sufficiently posteriorally so that the extending portions 6 and 6' fully cover the Temporalis ... the second group of back and neck muscles, the pad is positioned ... cover the upper Trapezius 214 while at the same time the central portion 2 of the pad fits about the neck and comfortably covers the Sternocleidomastoid 216, the Insertion of the Internal Pterogoid and the Molyhyoids ... The third position for applying therapeutic treatment to the third group of muscles of the neck and chest ... the additional length provided by the extending portions 6 and 6' permit them to drape over the chest to cover both the upper end of the Trapezius 214, the Cervical 218 and the upper Pectoralis 220. The cut-out

¹⁵ *Lipton*, col. 5, lines 17-18.

10 again permits the pad to comfortably conform to the neck such that the Sternocleidomastoid is covered.¹⁶

Finally, the Office Action provides that first, second and third substrates of Lipton may be made of any desired weight, density, etc. Nothing in *Lipton* teaches "an arcuate outer shell overlaying a cushioning substrate" as recited by claim 9, among other features; the "reversibly deformable material is integrally molded with said first substrate" as recited by claim 10, among other features; the "first substrate and the second substrate are integrally molded to each other" as recited by claim 12, among other features; the "first substrate is more rigid than the second substrate" as recited by claim 17, among other features; the "straps terminating with complementary closure means and each of said straps having a length sufficient to encircle the front of the neck" as recited by claim 19, among other features; or the "third substrate attached to one of said straps such that when the straps encircle the neck, the third substrate directly overlays a tracheal region of the neck" as recited by claim 20, among other features.

Claims 4 and 5 stand rejected under 35 U.S.C. §103(a) as being anticipated by *Lipton* in view of by Hujar et al, U.S. Patent No. 5,557,807 (hereinafter "*Hujar*"). Applicant traverses this rejection with respect to claims 4 and 5 and respectfully submits that the pending claims are allowable.

Claims 4 and 5 depend from amended independent claim 1, recite additional features thereto and are allowable therefore. Specifically, claim 4 recites a "device to protect the neck and the base of the skull of a person from injury during physical activities" in combination with "means for reversibly attaching to a helmet" among other features, while claim 5 recites a "device to protect the neck and the base of the skull of a person from injury during physical activities" in combination with "the device is integrally molded to a helmet" among other features. Neither claim is taught or suggested by *Lipton*, alone or in combination with *Hujar*.

The Office Action suggests that the combination of *Lipton* and *Hujar* was obvious. Specifically, the Office Action provides that "attaching the device to a helmet

¹⁶ *Lipton*, col. 4, lines 5-28.

as taught by Hujar an alternative but equivalent means of securing the device about the head in order to keep the user comfortable or depending on the end user thereof."¹⁷ Applicant disagrees, as the suggested combination is not obvious. The Federal Circuit has on a number of occasions addressed the issue of whether an alleged case of *prima facie* obviousness was properly made. The Federal Circuit has stated, "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination."¹⁸

Therefore, the fact that the prior art can be combined as suggested, does not render such combination obvious unless it is taught or suggested by the prior art. *Lipton* is directed to "a therapeutic treatment pad capable of being comfortably and safely positioned in at least three positions wherein all of the muscles of a given group are simultaneously and evenly treated."¹⁹ *Lipton* also specifically discloses "three muscle groups may be therapeutically treated by a single pad due to the unique shape"²⁰ as provided previously.

As part of the therapeutic pad, *Lipton* discloses, "straps 14 and 14' having Velcro ... comprise means for selectively connecting the opposite ends of the central portion to one another and to the extending portions"²¹ and "a generally semi-circular shaped cutout 10."²² The arrangement of the straps and cutout, among other features, provide for securing the *Lipton* device about the user's head. *Lipton* specifically discloses:

The provision of the cut out 10 permits the pad to be positioned sufficiently posteriorly so that the extending portions 6 and 6' fully cover the Temporalis ... the central portion 2 of the pad fits about the neck and comfortably covers the Sternocleidomastoid 216, the Insertion of the Internal Pterogoid and the Molyhyoids ... The third position for applying therapeutic treatment to the third group of muscles of the neck and the cut-out 10 again permits the pad to

¹⁷ Office Action, ¶ 5, page 4, lines 1-3.

¹⁸ *ACS Hospital V. Montefiore Hospital*, 732 F.2d. 1572, 221 USPQ 929, 933 (Fed. Cir. 1984).

¹⁹ *Lipton*, Col. 1, lines 54-58.

²⁰ *Lipton*, Col. 4, lines 38-40.

²¹ *Lipton*, col. 2, lines 65-68.

²² *Lipton*, col. 2, lines 59-60

comfortably conform to the neck such that the Sternocleidomastoid is covered.²³

In other words, *Lipton* discloses straps and a cutout adapted to position and secure the pad, enabling the pad to comfortably conform to the neck and treat the specifically disclosed muscle groups. However, neither *Lipton* nor *Hujart* disclose, nor does the Office Action identify, any need for attaching the therapeutic pad of *Lipton* to the helmet of *Hujar*. Applicant submits that such combination would result in a misalignment of the therapeutic pad as disclosed by *Lipton*, as the pad would be positioned too high on the user, and thus would not be properly aligned to treat the specifically disclosed muscle groups. Therefore the proposed combination is not suggested by the references.

Even if it is assumed, *arguendo*, that the individual teachings of *Lipton* and *Hujar* are indeed combinable, such a combination does not render the device of claims 4 and 5 obvious to one of ordinary skill in the art. At most, the combination of *Lipton* and *Hujar* disclose a therapeutic pad attached to a helmet and used to treat specific muscle groups after an injury (whiplash for example). The combination does not teach or otherwise suggest a "device to protect the neck and the base of the skull of a person" in combination with "means for reversibly attaching to a helmet" as recited by claim 4, among other features or a "device to protect the neck and the base of the skull of a person" in combination with "the device is integrally molded to a helmet" as recited by claim 5, among other features.

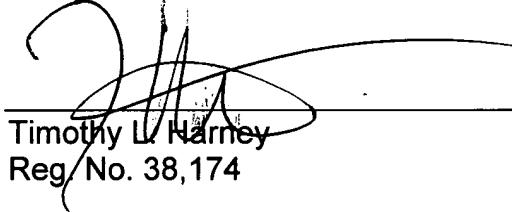
²³ *Lipton*, col. 4, lines 5-28.

In view of the foregoing, it is respectfully submitted that the pending claims define allowable subject matter. Should anything remain in order to place the present application in condition for allowance, the Examiner is kindly invited to contact the undersigned at the telephone number listed below.

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Respectfully submitted,

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